Chapter 18

Poisons and Dangerous Substances

There are a number of controls on the sale, storage, labelling and other dealings with those poisons which are not medicines.

The Poisons Act 1972 sets up a mechanism to designate substances as poisons, and to lay down rules on how they are to be treated.

THE POISONS BOARD

Section 1 of the Poisons Act creates an advisory committee (in reality a continuation of one established by earlier legislation, the Pharmacy and Poisons Act 1933).

The Board consists of at least 16 members. Five of them must be appointed by Royal Pharmaceutical Society of Great Britain, and one of these must be engaged in the manufacture of pharmaceuticals. Members hold office for 3 years. The Chairman is appointed by the Secretary of State.

POISONS LIST

The main task of the Board is to recommend to the Secretary of State which substances should be listed as poisons. *Section 2* of the Act creates a Poisons List, which is set out from time to time in a Poisons List Order. The list consists of two parts:

Part I is a list of poisons which can only be retailed from a pharmacy.
Part II is a list of poisons which can be sold from either a pharmacy or by a 'listed seller'.

LISTED SELLERS

A 'listed seller' is a person allowed by the local county or borough council to sell Part II poisons. The local authority can refuse permission if it believes the person is unfit. Names may also be removed from the list for non-payment of the retention fee. A court may remove a name from the list following a conviction which would make the person unfit to sell poisons.

Pharmacy Law and Practice. DOI: http://dx.doi.org/10.1016/B978-0-12-394289-0.00018-7

The local authority list must include particulars of the premises and the names of the persons listed. The permission is specific to the person. Up to two deputies may be named. The list is open to public inspection without charge.

The local authority is entitled to charge reasonable fees for inclusion and for retention.

Listed sellers may not use any title, emblem or description which might suggest he or she is entitled to sell poisons other than those in Part II.

Enforcement

Enforcement is shared between the GPhC and the local authorities, with the GPhC dealing with pharmacies.

Penalties

A person who fails to comply with the law relating to poisons is liable on conviction to a fine of up to £1000. Offences involving the misuse of titles or the obstruction of an inspector may incur a fine of £100.

When the offences are related to the sale or supply of a poison the employer remains liable even though an employee acted without his authority (*Section 8*).

Substances on the List

Only substances which appear on the Poisons List are legally poisons. Other substances, despite their toxicity, are not legally poisons.

Some poisons may only be sold by listed sellers when the poison is in a specified form. Some poisons may only be sold to certain categories of purchaser.

THE POISONS RULES

The detail of the law is found in the Poisons Rules, which categorise poisons into a number of Schedules. There are different rules governing each of the Schedules. The current law is found in the Poisons Rules 1982, SI No. 218, as amended by the Poisons Rules Amendment Order 1985. The rules also contain a number of general provisions which apply to all poisons.

General Requirements

Generally, poisons in Part I must be sold:

(1) by a pharmacist or person lawfully conducting a retail pharmacy business (RPB),

(2) at the pharmacy,
(3) by or under the supervision of the pharmacist.

Poisons in Part II must be sold:

(1) from a pharmacy, or
(2) by a listed seller from his premises.

Listed sellers may not sell any Part II poisons which they have altered or processed in such a way as to expose the poison.

Schedule I

Extra conditions are specified for the sale, storage and record-keeping of poisons in Schedule I.

Supervision

All Schedule I poisons, even those on Part II of the List, must be sold under the supervision of the pharmacist when sold from a pharmacy. When sold from 'listed premises' the sale must be effected by the listed seller or one of his deputies.

Storage

Schedule I poisons must be stored separately from other items. They must be in:

(a) a cupboard or drawer used solely for poisons, or
(b) a part of the premises separated from the rest so as to exclude the public, or
(c) on a shelf used only for storing poisons, and which has no food below it.

Schedule I poisons which are used in agriculture, horticulture or forestry must be kept separate from food products. If stored in a drawer or cupboard no other products may be kept with them.

When poisons are transported in vehicles, adequate steps must be taken to avoid contamination of any food carried in the same vehicle.

Knowledge of the Purchaser

Purchasers of Schedule I poisons must be known to the seller, or to a responsible person on his staff, as being 'of good character'. The person on the staff may be a pharmacist, or in the case of listed sellers, the person in charge of the premises or of the department.

Where the purchaser is not known, they must present a certificate stating that they are of good character. This must be in the prescribed form, and given by a householder. If the householder is not known to the seller then the

certificate must be endorsed by a police officer in charge of a police station. The endorsement certifies that the householder is known to the police as a person of good character. It does not itself certify the purchaser.

Records

Sellers of Schedule 1 poisons are required to keep a 'Poisons Book', and enter in it:

(1) date of sale
(2) name and address of purchaser
(3) name and address of person giving the certificate
(4) date of the certificate
(5) name and quantity of poison
(6) purpose for which the poison is stated to be required.

The format is laid down in Schedule 11 of the Poisons Rules.

The entry must be signed by the purchaser. Purchasers who require a poison for trade or professional purposes may present a signed order instead of signing the Poisons Book.

A Poisons Book must be retained for 2 years after the last entry.

Signed Order

A signed order must contain the following:

(1) name and address of purchaser
(2) trade, business or profession
(3) purpose for which the poison is required
(4) total quantity to be bought.

The seller must be reasonably satisfied that the signature is genuine, and that the person does indeed carry on the trade or profession stated.

The seller must retain the certificate, giving it a reference number for identification.

In an emergency a Schedule I poison may be supplied on an undertaking to supply a signed order in 24 h.

Relaxations

The requirements relating to knowledge of the purchaser and entries in the Poisons Book do not apply to the sale of poisons:

(1) for export
(2) by wholesale.

There are specific relaxations for the sale of nicotine dusts (less than 4%) and rat poisons containing barium carbonate or zinc phosphide.

SCHEDULE I POISONS SUBJECT TO EXTRA CONTROLS

The following Schedule 1 poisons are subject to extra controls:

Sodium and potassium arsenites
Strychnine
Fluoroacetic acid, its salts or fluoroacetamide
Thallium salts
Zinc phosphide.

They may only be sold or supplied:

(a) by wholesale
(b) for export
(c) for education, research or analysis.

These poisons may also be sold or supplied in the circumstances outlined below.

In September 2006, a new EU law regulated a wide range of poisons, including strychnine, to ensure they were safe and had no harmful effect on the environment.

Strychnine and strychnine hydrochloride is no longer authorised for supply or use for mole control.

Fluoroacetic acid, its salts or fluoroacetamide may be sold to a person with a certificate authorising the use as a rodenticide. The certificate must state the quantity and identify the place where it is to be used.

It may only be used in ships, sewers, drains and dock warehouses. Certificates are issued by local authorities or port health authorities or by DEFRA.

Thallium salts may also be sold to:

(a) local authorities or port health authorities,
(b) government departments,
(c) persons with a written authority issued by MAFF authorising the use of thallium sulphate for killing rats, mice or moles for pest control,
(d) manufacturers who regularly use them in the manufacture of articles in the business (except thallium sulphate),
(e) persons as an ingredient in any article not intended for consumption by persons or animals (except thallium sulphate).

Zinc phosphide may be sold:

(a) to a local authority,
(b) to a government department,
(c) to a person for his trade or business.

Calcium, potassium and sodium cyanides may only be sold under the so-called *Section 4* exemptions. Sales are not allowed for private purposes.

Section 4 Exemptions

Exempted transactions of Part 1 poisons may be made without pharmacist supervision, provided the sales are not made on retail premises:

- wholesale dealing,
- export,
- to doctor, dentist, vet for professional purposes,
- for use in hospital or similar public institution,
- sale by wholesale to:
  - government department,
  - for education or research,
  - enable employers to meet any statutory obligation with respect to medical treatment of employees,
  - a person requiring the substance for trade or business.

THE CHIP4 REGULATIONS 2009

All poisons must be labelled and packaged in accordance with the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 SI No. 716.

The regulations require the manufacturer or distributor of a 'chemical' to decide if it is 'hazardous' and then to label it appropriately and to supply a safety data sheet.

Background

Two European Directives establish a single market for the supply of chemicals in the EU by harmonising rules on how to classify, label and package hazardous chemicals. They are:

- Dangerous Substances Directive (No. 67/548/EEC), and
- Dangerous Preparations Directive (No. 1999/45/EC).

The Directives are implemented in Great Britain by the 'CHIP4' Regulations. There are similar regulations in Northern Ireland.

Classification

'Chemical' includes solids, liquids and gases and includes pure chemical substances such as ethanol as well as preparations of chemicals such as cleaning fluid. They are classified as follows:

(1) Chemicals which are dangerous because of their physical or chemical properties: explosive, oxidising, extremely flammable, highly flammable, flammable.
(2) Chemicals which are toxic, very toxic, harmful, corrosive, irritant or carcinogenic, mutagenic or toxic to reproduction.
(3) Chemicals which are dangerous for the environment.

Information

When classified chemicals are supplied in connection with work they must be accompanied by a 'safety data sheet'. Should any new safety information become available, the data sheet must be revised and copies given to anyone who obtained the chemical during the previous 12 months. There is thus an implicit requirement to keep records of sales for use in connection with work.

The information in the data sheets must be given under standard headings.

Labelling

The regulations set out details of labelling which include:

- the name and address of supplier
- name of the chemical
- the type of danger
- warnings about use
- EU number
- warning pictograms.

Packaging

Chemicals must be packaged safely. Toxic, very toxic and corrosive chemicals which are sold to the public must be in containers with child-resistant closures. This applies regardless of the quantity. It also applies to solid products. Tactile danger warnings must be on containers sold to the public of chemicals which are harmful, highly flammable, extremely flammable, toxic, very toxic or corrosive.

Advertisements

Adverts must mention the type of hazard that is mentioned on the label.

Exemptions

Some products are exempt from the CHIP Regulations because they are controlled in other ways, for example radioactive substances. The CHIP Regulations do not apply to preparations intended for use as cosmetics or medicinal products.

Future Legislation

On 1 June 2015, the European Regulation (EC) No. 1272/2008 on the Classification, Labelling and Packaging of Substance and Mixtures (CLP Regulation) comes into full effect. It will replace and fully repeal the Dangerous Substances Directive and the Dangerous Preparations Directive.

The CLP Regulation is directly acting in all EU Member States and does not require separate implementation into national law. The CHIP4 Regulations will remain in force throughout the transitional period of the CLP Regulation but, with the exception of Regulation 14 (enforcement), will also be repealed on 1 June 2015.

THE ENVIRONMENTAL PROTECTION ACT 1990

This Act places a duty of care on 'waste producers' to dispose of 'controlled waste' legally.

Waste producers are persons in business, but not householders where their own waste is concerned.

The Hazardous Waste (England and Wales) Regulations 2005 SI No. 894 came into effect on 16 July 2005.

Every person who produces or stores hazardous waste must notify the Environment Agency, except where the premises are 'shop premises' and the waste arises as a result of the activity of the shop. Thus a pharmacy which dispenses prescriptions, and accepts waste from individuals and households, will be exempt from notification requirements.

Different types of hazardous waste may not be mixed. Hazardous waste may not be mixed with non-hazardous waste.

The Controlled Waste (England and Wales) Regulations 2012 classify waste as household, industrial or commercial waste, and list the types of waste for which local authorities may make a charge for collection and disposal.

'Clinical waste' means waste from a healthcare activity (including veterinary healthcare) that:

(a) contains viable micro-organisms or their toxins which are known or reliably believed to cause disease in humans or other living organisms,
(b) contains or is contaminated with a medicine that contains a biologically active pharmaceutical agent, or
(c) is a sharp, or a body fluid or other biological material (including human and animal tissue) containing or contaminated with a dangerous substance within the meaning of Council Directive 67/548/EEC,

and waste of a similar nature from a non-healthcare activity.

Clinical waste is classed as 'industrial' unless the premises that produce the waste are domestic properties. The clinical waste from a care home (nursing) is industrial waste. Residential homes are included in an exemption and their waste is classed as 'household' even though the name has changed to 'care home'.

'Hazardous waste':

(a) in relation to England, has the meaning given in Regulation 6 of the Hazardous Waste (England and Wales) Regulations 2005(7);

(b) in relation to Wales, has the meaning given in Regulation 6 of the Hazardous Waste (Wales) Regulations 2005(8).

'Offensive waste' means waste that:

(a) is not clinical waste,
(b) contains body fluids, secretions or excretions, and
(c) falls within code 18 01 04, 18 02 03 or 20 01 99 in Schedule 1 to:
  (i) the List of Wastes (England) Regulations 2005, in relation to England, or
  (ii) the List of Wastes (Wales) Regulations 2005 in relation to Wales.

A community pharmacy may legally act as an intermediary in the process of medication disposal only for care homes offering personal care.

Cytotoxic and Cytostatic Medicines

The Hazardous Waste Regulations classify cytotoxic and cytostatic medicines as clinical hazardous waste and include any medicine that has one or more of the hazardous properties toxic, carcinogenic, mutagenic and toxic for reproduction. This wide definition includes many hormone-based preparations, antimicrobial substances such as chloramphenicol as well as chemotherapy.

Pharmacies must therefore segregate their waste medicines into:

- cytotoxic and cytostatic medicines, and
- other medicines.

The regulations require that pharmacies:

(1) keep hazardous waste separate, and
(2) place a duty on a pharmacy to separate mixed waste, provided it is safe and practical to do so.

MEDICINES RETURNED FROM DOMESTIC PREMISES

The DH guidance 'Safe management of healthcare waste 2011'[1] is that domestic households (which are not subject to the prohibition on mixing) may return mixed waste medicines to the pharmacy.

All reasonable steps should be taken to segregate the medicines, bearing in mind the health and safety implications.

Where possible, the returned medicines should be either examined in the container or emptied temporarily onto a tray (which will contain the waste and avoid spillage onto other surfaces).

This may be necessary to identify if controlled drugs are present.

Identifying individual loose tablets is often impracticable and is not required.

The provision of a disposal service in respect of unwanted drugs is an Essential Service set out in *Paragraphs 13* and *14* of Schedule 4 to the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013:

An NHS pharmacist must, to the extent paragraph 14 requires and in the manner described in that paragraph, accept and dispose of unwanted drugs presented to the NHS pharmacist for disposal.

Controlled Drugs

Since 1 January 2007, the Controlled Drugs (Supervision of Management and Use) Regulations 2006 have required pharmacies in England to have SOPs that include arrangements for recording the return of Schedule 2 controlled drugs from patients, and recording the denaturing of such drugs.

COSHH

The Control of Substances Hazardous to Health Regulations 2002 SI No. 2677 affects the use of hazardous substances in a work situation, by laying down measures which an employer must take to control hazardous substances and to protect people who are exposed to such substances.

Regulation 6 requires that an employer may not carry on any work that is liable to expose any person to any substance hazardous to health, unless a suitable and sufficient assessment of the risks has been made.

What Is a Substance Hazardous to Health?

A substance hazardous to health is defined as:

> *any natural or artificial substance: solid, liquid, gas, vapour or hazardous micro-organism and certain dust levels.*

Substances hazardous to health can include:

(1) any substance classed as:
toxic, very toxic, harmful, corrosive or irritant.
(2) any micro-organism,
(3) any dust,
(4) any substance which has a prescribed maximum exposure limit, e.g., formaldehyde,
(5) any other substance which can adversely affect the health.

Helpfully, the regulations state that a substance is NOT hazardous when it is at a level that nearly all the population can be exposed to it, repeatedly, without ill effect.

Certain situations are specifically excluded from COSHH:

(a) those covered by the Control of Lead at Work Regulations 1980,
(b) those covered by the Control of Asbestos at Work Regulations 2002,

(c) when the hazard is radioactivity,
(d) when the hazard is the explosive or flammable properties of the substance,
(e) underground mines,
(f) medicines administered to patients.

What Must the Employer Do?

The employer must first of all decide whether or not any substance is potentially hazardous. This must be done by a competent person.

The employer must then:

(1) assess the risk to health from the use of the substance in the workplace,
(2) decide what precautions are needed,
(3) introduce appropriate measures to control the risk,
(4) tell employees about the risk, and about what precautions must be taken,
(5) ensure that precautions are taken,
(6) if appropriate, monitor the exposure and carry out health surveillance.

Assessment

The assessment must be carried out by a competent person. The results of the assessment must be made available to staff.

If the assessment indicates a risk, then the employer must take steps to prevent exposure. If prevention is impossible then the exposure must be reasonably controlled. (Regulation 7)

PACKAGING WASTE

The Producer Responsibility Obligations (Packaging Waste) Regulations 1997 SI No. 648 implement the European Directive 94/62/EEC on the recycling of waste. The regulations are made under the Environment Act 1995.

The regulations place a 'producer responsibility' on businesses involved in the packaging chain to recover and recycle certain percentages of packaging waste. The obligation applies to businesses with a turnover of more than £5 million a year and which handle more than 50 tonnes of packaging a year. Packaging which contained 'special waste' is partially exempted from the regulations. Smaller businesses are subject to a requirement to keep records of the tonnage of waste handled each year and of any steps taken to promote the recovery of this packaging.

DANGEROUS SUBSTANCES AND EXPLOSIVE ATMOSPHERES REGULATIONS 2002

These regulations require businesses to carry out risk assessments when using potentially dangerous substances. They must provide measures to eliminate or reduce as far as possible the identified explosion or fire risks.

FOOD SAFETY ACT 1990

The Food Premises (Registration) Regulations 1991 require all premises which sell food to be registered with the local authority. It is an offence to use unregistered premises for a food business. Food includes packed baby foods, confectionery, etc.

The General Food Regulations 2004 require food retailers to keep records of the source of food items. Details of the purchaser must be kept if the supply is a wholesale one. Food includes baby foods, baby milks and dietary supplements which are not medicinal products.

THE OFFENSIVE WEAPONS ACT 1996

Section 6 of the Act prohibits the sale of knives and similar objects to people under 16 years old. The prohibited items include 'any knife blade or razor blade' and 'any other article which has a blade or is sharply pointed and which is made or adapted for causing injury to the person'. Items in pharmacies which might fall within these wide definitions include corn knives, metal nail files, scissors and the like.

Self-Assessment Questions

1. What are the general requirements for the sale of poisons in a pharmacy?
   Answer: Generally, poisons in Part I must be sold at the pharmacy by a pharmacist or person lawfully conducting an RPB or under the supervision of the pharmacist. All Schedule I poisons, even those on Part II of the list, must be sold under the supervision of the pharmacist when sold from a pharmacy.
2. How might the COSHH rules apply to pharmacies?
   Answer: The Control of Substances Hazardous to Health Regulations 2002 SI No. 2677 affect the use of hazardous substances in a work situation, by laying down measures which an employer must take to control hazardous substances and to protect people who are exposed to such substances. The regulations require that an employer may not carry on any work that is liable to expose any person to any substance hazardous to health, unless a suitable and sufficient assessment of the risks has been made. A substance hazardous to health includes any substance classed as toxic, very toxic, harmful, corrosive or irritant. This can also include cytotoxic drugs. Thus the COSHH regulations apply when staff is sorting returned medicines for disposal. In such a situation the employer must then:
   1. assess the risk to health from the use of the substance in the workplace,
   2. decide what precautions are needed,
   3. introduce appropriate measures to control the risk,
   4. tell employees about the risk, and about what precautions must be taken,
   5. ensure that precautions are taken,
   6. if appropriate, monitor the exposure and carry out health surveillance.

3. How does the Offensive Weapons Act 1996 apply to pharmacies?
   Answer: *Section 6* of the Act prohibits the sale of knives and similar objects to people under 16 years old. The prohibited items include 'any knife blade or razor blade' and 'any other article which has a blade or is sharply pointed and which is made or adapted for causing injury to the person'. Items in pharmacies which might fall within these wide definitions include corn knives, metal nail files, scissors and the like.

ADDITIONAL RESOURCE

1. http://www.spaceforhealth.nhs.uk/England/topics/health-technical-memorandum-07-01-%E2%80%93-safe-management-healthcare-waste